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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,294

04/12/2004

Kent Voorhees

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,294	Applicant(s) VOORHEES ET AL.	
	Examiner ZACHARIAH LUCAS	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10-15 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 14, 15, and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-3, 10-15, and 21-23 are pending and allowed in the application.
2. In the prior action, mailed on April 25, 2008, claims 1-23, 32-48, 50, 51, 53-58, 62-70, 73, 84-86, and 95-99 were pending, with claims 8-13, 16-20, 33, 35, 36, 40-45, 51, 53-58, 62-70, 73, 86, and 95-99 withdrawn from consideration; claims 1-7, 14, 15, 21-23, 37-39, 46-48, 50, 84, and 85 under consideration and rejected.
3. In the amendment of August 25, 2008, the applicant amended claim 21; and cancelled claims 4-9, 16-20, 32-48, 50, 51, 53-58, 62-70, 73, 84-86, and 95-99.
4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3, 2008 has been entered.

In the submission, Applicant amended claim 21.
5. Claims 1-3, 14, 15, and 21-23 are under consideration.
6. In view of the restatement and addition of new double patenting rejections, the action is made Non-Final.

Claim Rejections - 35 USC § 112

7. **(Prior Rejection- Withdrawn)** Claims 21-23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the amendment to claim 21, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejection- Maintained)** Claims 46-48 and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (WO 98/08944) in view of U.S. 5,789,174 (Mouton). In view of the cancellation of these claims, the rejection is withdrawn.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **(Prior Rejection- Restated and Maintained)** Claims 1-3, 7, 14, 15, 37-39, 84, and 85 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673.

Applicant traverses the rejection on the basis that the indicated claims of the copending application have been cancelled. In view of the argument, the rejection is restated as a rejection of claims 1-3, 14, and 15 over claims 11-14, and 17-24 of the copending application.

While the copending claims are drawn to methods of determining an initial quantity of the target microorganism in a sample, performing the assay would also inherently determine the presence or absence of the microorganism. Moreover, claim 20 is specifically drawn to embodiments wherein the parent phage (equivalent to the phage of part (a) in the present claims) is added to the sample in an amount below the detection limit of the phage. It would have been obvious to those of ordinary skill in the art that this meant that the phage was added in an amount below the threshold amount capable of being detected by the relevant detection assay or device. The copending claims would therefore anticipate the present claims if applied as prior art. The present claims are therefore rejected for obviousness type double patenting over those claims.

The rejection is therefore maintained for the reasons above, and the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. **(Prior Rejections- Withdrawn)** Claim 5 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673 in view of Rittenburg et al. (US 5,710,005). Claim 34 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673 in view of Pearson et al. (U.S. 5,476,768). These claims have been cancelled from the application. The rejection is therefore withdrawn.

13. **(New Rejection)** Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 46-56 of copending application 11/626326. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims represent a species of the presently claimed methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Because both applications claim priority to the same parent applications, neither is the earlier filed application. Thus, a TD is required in the present application before the rejection may be withdrawn.

14. **(New Rejection)** Claims 1-3, 14, 15, and 21-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over either of claims 11-14, and 17-24 of copending application 11/698,673, or of claims 1 and 46-56 of copending application 11/626326, further in view of Rees et al. (WO 92/02633- of record in the action

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mailed in July 2007). These claims read on the claimed methods, wherein the methods involve lysing the target microorganism (such as by permitting the phage to burst the microorganism) prior to the assaying, and wherein the method includes dissociating the phage in the bacteriophage exposed sample such as by adding an acid to the sample.

The copending claims read on a method such as that described by claims 1-3. However, the claims of the '326 application do not specify the lysing of the target microorganism, or the dissociation of the phage, and the claims of the '673 application do not teach the dissociation of the phage.

Rees also teaches a method for the detection of a target bacterium through the use of phage. Abstract. . The method involves the addition of phage to a sample to infect the target bacteria, amplifying phage in the sample (i.e. permitting them to replicate in the target bacteria), and detecting the resulting phage. Abstract. The reference indicates that the progeny phage may be detected through the use of an immunoassay (pages 6-7), or through the use of a plaque assay (which requires that the infected bacteria are lysed through phage induced bursting). The reference also teaches the dissociation of phage after infection but before lysis and assaying (i.e. during step (b) of the claimed methods), including embodiments wherein the dissociation is through use of an acid. Page 6, lines 10-13, and page 8, lines 16-18. From these teachings, it would have been obvious to those of ordinary skill in the art to incorporate such methods into the methods of the copending claims, as a means for the assaying of the phage infected sample for a biomarker associated with the progeny phage. The present claims therefore represent obvious variants of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Because both the present and the '326 applications claim priority to the same parent applications, neither is the earlier filed application. Thus, a TD is required in the present application before the rejection may be withdrawn.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARIAH LUCAS whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648